# Chapter 3 - General Institution

## AP 3260 Institutional Review Board

**References:**

Code of Federal Regulations (CFR), Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP), National Science Foundation (NSF); Title 45 part 46; Title 45 part 690; 45CFR part 690 §.107; 45CRF46.102.

The College conducts research on its students and employees through its normal day-to-day operations. External researchers also ask to conduct research at the College. In order to protect students, employees, and the community, the College has a district-level Institutional Review Board (IRB).

The IRB for Human Subjects Research at Mt. San Antonio Community College has responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. In addition to serving as an active resource regarding research ethics, the Institutional Review Board (IRB) also guides the College's research ethics, progress, and processes. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study, consent to be a subject in the study, and are debriefed as necessary; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, any risk to the participants, and evaluating the alignment of the study with the College's Mission. To safeguard the well-being of human subjects, meet (federal) guidelines, and protect the College, the IRB is entrusted with the coordination of training for faculty, staff, management, and external researchers to keep them apprised of the most updated research ethics standards, policies, and procedures.

The IRB adheres to the federal regulations of protecting human subjects. The IRB is an ethics committee composed of at least five individuals who serve as advocates for human subjects involved in research and who have varying expertise and diversity including at least one individual from the community and one nonscientist as outlined in regulations (45CFR part 690 §.107).

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of Mt. San Antonio College's mission, regulations, relevant law, ethical

standards, and standards of professional practice. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the educational research that it reviews. External or internal consultants may be used to review proposals for which additional expertise is needed. The gender and ethnic makeup of the members should be taken into consideration, and there should be a member with knowledge of disabled student issues and regulations. There is to be one member from the community. Due to federal regulations set forth regarding the preferred expertise and training of committee members, members will be recommended by the District as well as the Academic Senate for appointment with the number of faculty appointed to be at least five. CSEA may appoint one nonscientist to the IRB. Each IRB member shall have an alternate* to ensure that vacancies can be filled quickly and efficiently when the need arises. Given the extensive training requirements for IRB membership, trained alternates for each IRB member are needed so not to disrupt the work of the IRB when a vacancy does occur.

**tentative: needs PAC approval*

Initial Review

The initial review requires the IRB Co-Chairs to review all petitions for research projects and evaluate them relative to the criteria set forth by the committee. The projects could be categorized into one of the following: (1) exempt from review; (2) requires an expedited review; or (2) requires a full board review by the IRB.

Exempt

Under the auspices of the IRB, the IRB Co-Chairs will review the Mt. SAC IRB Application Form eligible for exempt or expedited review if there is no or minimal risk. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified. Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise; see: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm as indicated below:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The IRB Co-Chairs, not the investigator, shall make the recommendation as to whether a project is or is not exempt. The IRB determines if a study is exempt and reports on all approved exemptions to the Vice President, Instruction.

<u>Expedited Review</u>

Under federal regulations, certain types of research qualify for an 'expedited' review (see http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm). These are activities that: (1) present no more than minimal risk to human subjects; and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

1. Clinical studies of drugs and medical devices.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. Prospective collection of biological specimens (e.g., hair and nail clippings) for research purposes by noninvasive means.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where the above categories two (2.) through eight (8.) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB Co-Chairs may recommend a protocol to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full Board. The IRB Co-Chairs cannot “disapprove” of a protocol but may table action pending further information/clarification. The IRB Co-Chairs will inform the Principal Investigator (PI) of its actions. Any disagreement between the PI and the IRB Co-Chairs must be resolved by the full IRB. The PI may request a Full Board Review of any denied research request. The IRB authorizes the Co-Chairs to approve an expedited review research projects at the College and reports on all approved requests to the Vice President, Instruction. The IRB shall provide an informational report to the President’s Advisory Council, quarterly.

## Full Board Review

If there is considered to be significant risk to the participants of the study, that is inherent in the study, then it requires a petition to the IRB for full Board review. Mt. San Antonio College discourages research requests of this nature. Studies in this category may be considered by the IRB only if they are clearly in alignment with the mission of the College. The PI must receive formal approval from the IRB, as well as sign appropriate paperwork with the Research and Institutional Effectiveness Department, before engaging in any research activity on campus. The IRB authorizes expedited review research projects at the College and reports on all approved requests to the Vice President, Instruction.

## Meetings and Approvals

The IRB will meet monthly during the Fall and Spring semesters. The Co-Chairs of the IRB will make decisions and inform the IRB regarding studies that are exempt or expedited, but the IRB shall make the final decision on research studies requiring full Board review.

If and when deemed appropriate, the IRB can choose to share the results of a particular study in conjunction with the PI.

The IRB webpage will contain all documents needed by both the IRB and researchers.

## Blanket Approval

Each Fall Semester, the IRB will work with the District to create and review a blanket IRB for its exempt and/or expedited activities under the Research and Institutional Effectiveness Department.

Approved: August 22, 2012
Reviewed: May 14, 2013
Reviewed: December 6, 2014
Revised: March 25, 2015
Reviewed: August 17, 2016